



Preparing for analysis

AFINION[™] HbA1c Test Cartridge

- Store the test kit refrigerated (2-8°C) until the expiry date or at room temperature (15-25°C) for maximum 90 days.
- The test cartridge must reach a temperature of 18-30°C before use; leave the unopened foil
 pouch on the bench for at least 15 minutes.
- Use the test cartridge within 10 minutes after opening the foil pouch.
- Hold the test cartridge by the handle.

Patient Sample

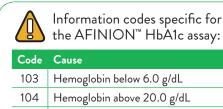
- Use capillary blood directly from finger, or venous whole blood (with EDTA, heparin, citrate or NaF).
- Venous whole blood with anticoagulants (except NaF) can be stored refrigerated (2-8°C) for 10 days or at room temperature (18-30°C) for 8 hours. Capillary samples cannot be stored.
- Mix the sample by inverting the tube 8-10 times before use.

AFINIONTM HbA1c Control

- Store the controls refrigerated (2-8°C). Opened controls are stable for 60 days.
- Allow the control to reach a temperature of 15-25°C before use, which takes approximately 45 minutes.
- Mix the control thoroughly by shaking the vial for 30 seconds before use. A whirl mixer may be used.
- The measured value should be within the acceptable range stated in the Afinion[®] HbA1c Control Package Insert.

AFINION[™] 2 Analyzer

- Switch on the analyzer and optionally enter the operator ID.
- Analyse patient samples and controls following the test procedures on the reverse side.
- An information code might be displayed during analysis. The possible causes and actions to take are listed in the AFINION[™] 2 Analyzer User Manual.



HbA1c below measuring range

HbA1c above measuring range

105

106

i

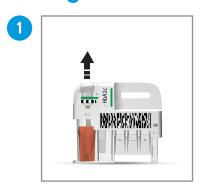
Consult the AFINION[™] User Instructions for complete information:

- Afinion HbA1c Package Insert.
- Afinion HbA1c Control Package Insert.
- AFINION 2 Analyzer User Manual.

AFINION[®] HbA1c

QUICK REFERENCE GUIDE

Testing Procedure



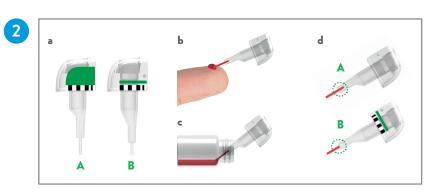
Pull the sampling device straight up from the test cartridge.



Replace the sampling device immediately. Analysis of the test cartridge must start within 2-3 minutes.



Touch 📿 and enter patient ID, or touch 🚺 and enter control ID. Touch 🔶 to confirm.



The Afinion HbA1c Test Cartridge is equipped with either of the two models A or B of the sampling device (a). The two models have slightly different shape, but the filling volume of the capillary and the handling of the device is exactly the same.

Fill the capillary completely (d) with patient sample (b) or control (c).



Touch 😰 for patient samples, or touch 🛒 for controls. The lid opens automatically.



Record the result when it appears on the screen. Touch \checkmark to accept. The lid opens automatically.



Insert the test cartridge with the barcode facing left. Close the lid manually to start analysing.



Remove and immediately discard the used test cartridge. Close the lid manually when the analyzer is not in use.



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